PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Stuart A. Lipton
Serial No.: 08/346,910
Filed : November 30, 1994
Title : PROTEIN 68075 AND ITS USE FOR REGENERATING NERVE CELL PROCESSES

Art Unit: 1812
Examiner: S. Cermak

Commissioner of Patents and Trademarks
Washington, DC 20231

DECLARATION OF DR. STUART A. LIPTON UNDER 37 C.F.R. §1.132

I, STUART A. LIPTON, declare:

1. I am the inventor of the subject matter claimed in the above-captioned patent application and its predecessors, including the great grandparent case, USSN 07/371,779 (the '779 application").

Reference to and chain of custody of clone TR2B

2. USSN '779 and subsequent continuation applications disclose several clones that were obtained before August 9, 1989. One of these clones (ATCC 68075) is referenced by that number in the '779 application, and it was obtained as described therein. Specifically, I requested Dr. Rachael Neve to screen a library she had constructed for other reasons, using anti-THY-1 anti-idiotypic antibodies. When she did so, she obtained ATCC 68075 (then called TR1-3D). I further requested her to rescreen that library using ATCC 68075. When she did so, she obtained other clones, including one designated TR2B. She told me that she had

Date of Deposit March 20, 1995
I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Kathleen M. O'Shea

Kathleen M. O'Shea

obtained those clones. At p. 9, lines 1-3 of the '779 application, I specifically referenced the clones which Dr. Neve obtained upon rescreening. In May, 1990, at my request, Dr. Neve sent those clones to Dr. Leifer in my laboratory. In August, 1993, Dr. Leifer moved to Yale and took the clones, including TR2B with him. In the fall of 1994, I requested Dr. Krainc of my laboratory to obtain TR2B from Dr. Leifer and to deposit it with the A.T.C.C.

Leifer et al. PNAS (USA) 90:1546-1550 (1993), and the biological role of clone TR2B

3. I have read the Office Action mailed December 14, 1992.

4. Exhibit A to this Declaration is a copy of Leifer et al., *Proc. Nat'l. Acad. Sci. USA* 90:1546-1550 (1993). The cDNA described in Exhibit A as "a cDNA clone corresponding to amino acids 140-238 of hMEF2C" (page 1546, to of second column) is the clone deposited with the ATCC on August 9, 1989 as Deposit #68075. Exhibit A documents that ATCC deposit #68075 was used to re-screen the same human fetal brain cDNA library, described in paragraph 2, above.

5. Figure 2D of Exhibit A also documents that the protein according to the invention could directly regulate transcription of genes with an upstream MEF2 enhancer sequence or indirectly regulate translation by way of interactor sites or other mechanisms.

6. Based on such transcription enhancement, and the experimental results using the gene encoded by clone TK2B described in the accompanying Declaration of Dimitri Krainc, one skilled in the art would predict that differential expression of this protein accompanies and directs neuronal differentiation and maturation, especially in the process of cortical lamination. On that basis, I conclude that the protein according to the invention will effect neural regeneration when used as directed in the specification.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Stuart A. Lipton, M.D., Ph.D.

Date: 3/15/95

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